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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/840,257 04/23/01 SCOTT

R 6512-11EJF

WARNER-LAMBERT COMPANY  
201 TABOR RD  
MORRIS PLAINS NJ 07950

IM22/0828

EXAMINER

HON. S

ART UNIT

PAPER NUMBER

1772

DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/840,257	Applicant(s) SCOTT ET AL.	
	Examiner Sow-Fun Hon	Art Unit 1772	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☒ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                              |                                                                             |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other:                                          |

Art Unit: 1772

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 24, 26-28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n).

### ***Claim Rejections - 35 USC § 101***

2. Claims 29-30 provide for the use of a composition and manufacturing step, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 29-30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the phrase "by weight by a water content ...." means. The examiner

Art Unit: 1772

will take the position that there is a comma missing between the “by weight” and “by a water content” and will examine the claims in that light. In addition, it is unclear what the % by weights are referred to. The examiner will take the position that the reference is the capsule film itself. Correction is required.

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation “the hydrocolloids are contained in an amount of 0.01 to 10 %” and the claim also recites “preferably 0.05 to 5 % by weight” which is the narrower statement of the range/limitation. In addition, claim 4 also recites the broad recitation “cations in amount of 0.001 to 5 %” and the narrower range/limitation 0.01 to 3 % by weight”. The use of “preferably 0.05 to 5 % by weight” and “preferably 0.01 to 3 % by weight” claim language does not positively recite the amounts by weight of hydrocolloids and cations, and is therefore indefinite. Correction is required.

Art Unit: 1772

7. Claims 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what process, and which sequence of the process, the two improperly worded processing steps are part of. Correction is required.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 10, 13-30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cade et al. (WO 97/04755). Cade discloses an aqueous solution of polyvinyl alcohol and a setting agent (column 6, lines 1-11), wherein the setting system consists of hydrocolloids and cations (setting agents), Kappa carrageenan and KCL (where the K is the potassium cation in the chemical terminology), (column 6, lines 8-9). The amount of Kappa carrageenan and KCl was in the amount of 0.05 to 2 % (column 6, lines 8-13), and the amount of water is given in an example to be from 2 to 7 % (column 15, lines 16-18). Carrageenan is an exocellular polysaccharide.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1772

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al. in view of Yamamoto et al. (US Patent 5,264,223). Cade et al. have been discussed above and fail to disclose specify the amounts of the composition and the use of claimed list of polysaccharides as hydrocolloids.

Yamamoto et al. have a capsule for pharmaceutical use (title). The capsule comprises a water-soluble cellulose derivative and a gelatinizing (setting) agent (abstract). The setting agent disclosed are polysaccharides such as carrageenan and the cations listed (column 3, 1-20). Yamamoto et al. also disclose hydrocolloids such as polysaccharides of tamarind seed (tamarind gum) and curdlan (column 3, lines 1-4). In addition, Yamamoto et al. also teach the amount of setting agent to be 0.1 to 0.5 % by weight, the amount of cation (auxilliary) to be 0.01 to 0.5 % by weight and the amount of water to be 4 to 6 % by weight of the capsule film (column 4, lines 26-32).

Because Yamamoto et al. demonstrate that the specific polysaccharides and compositions comprising them are well known in the art, it would have been obvious to one of ordinary skill in the art to have used the specific teachings of Yamamoto et al. in the invention of Cade et al. to obtain a specific capsule film.

12. Claims 3, 5, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al. in view of Gilbert et al. (US Patent 4,349,563). Cade et al. have been discussed above and fail to teach the use of sequestering agents.

Art Unit: 1772

Gilbert et al. have pharmaceutical compositions (title) which can be polyvinyl alcohol compositions which contain trisodium citrate (column 9, lines 9-18 and column 10, lines 29-36) designated as one of the sequestering agents in a list (column 2, lines 45-54), in the amount of 0.001 to 2 % by weight of the composition.

Because Gilbert et al. demonstrate that the claimed sequestering agent is well known in the art, it would have been obvious to one of ordinary skill in the art to have used the teachings of Gilbert et al. in the invention of Cade et al. in order to obtain a capsule film for the desired end-use.

13. Claims 13-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al. in view of Yamamoto et al. and Gilbert et al. All three inventions have been discussed above.

In addition, Cade et al. is directed to a gelatin capsule where a polymer layer is laminated (coated) on to a gelatin shell and/or at least one additive is added to a gelatin formulation during the gelatin capsule production (abstract). Cade et al. teach that the amount of additive content in the gelatin can be from 1 to 50 % (column 8, lines 1-5), that the number of additives can be one or more, and that the additives can be plasticisers (column 8, lines 6-9). The plasticisers can be glycerol, dioctyl -sodium sulphosuccinate, triethyl citrate, tributyl citrate, 1,2-propyleneglycol, mono-, di- or triacetates of glycerol in concentrations of about 0.5 to 40 % by weight of polymer (column 9, lines 10-17). The dyes can be azo-, indigold, quinophthalone, triphenylmethane and xanthene, carotenoids (carotenes), flavones, titanium dioxide, carbon (black) and iron oxides (column 8, lines 12-24), and in concentrations of 0.001 to 10 % by weight of the polymer which is gelatin (cellulose ether), (column 9, lines 24-30).

Art Unit: 1772


Because Yamamoto et al. and Gilbert et al. demonstrate that the claimed compositions and agents are well known in the art, it would have been obvious to have used the specific teachings of Yamamoto et al. and Gilbert et al. in the invention of Cade et al. in order to obtain a capsule product with the desired end-use.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH  
08/24/07

  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  
1772

8/27/01